IC: _____			
	ANNUAL INTRMAURAL SELF ASSESSMENT OF MANAGEMENT CONTROLS		
	PERIOD OF REVIEW: FY2005		
	SCIENTIFIC STAFF COVERED BY ASSESSMENT: All Scientific Staff with IPD from Senior Investigator to Student (including Contract Staff)		
Program and Project Planning Management			
A. Protection of Human Subjects and Standards for Clinical Research			
		Yes	***No***
1	Do you have access to a duly constituted IRB, established in accordance with the NIH Policy Manual 3014 - NIH Human Research Protection Program? (http://www1.od.nih.gov/oma/manualchapters/intramural/3014/)		
1a.	Are the IRB records maintained in accordance with the NIH Policy Manual 3014 - NIH Human Research Protection Program? (http://www1.od.nih.gov/oma/manualchapters/intramural/3014/)		
1b.	Where? (Bg. # , Room #)		
1c.	Secured by whom? Name:		
2	Has your IC received any allegations of non-compliance with the NIH Policy Manual 3014 - NIH Human Research Protection Program? (http://www1.od.nih.gov/oma/manualchapters/intramural/3014/)		
2a.	If yes, please explain:		
3	How many new protocols has your IRB reviewed during FY2005? #:		
3a.	How many new protocols has your IRB disapproved or deferred/tabled during the period of review? #:		
4	How many of the following types of protocols are active in your IC?		
	Research: Clinical Trial: Screening:		
	Research: Natural History/Epidemiology: Training:		

5	Were all patients seen in your IC Clinical Program covered by a written, active protocol?		
	If NO, please describe situations to justify such exceptions:		
6	Who at the NIH has oversight responsibility to assure that patients sign and receive copies of informed consent documents? Name and phone number:		
7	Were all IRB annual continuing reviews completed within 30 days of their scheduled review?		
8	Does your IRB follow the NIH standard operating procedures in accordance with NIH Policy Manual 3014 - NIH Human Research Protection Program? (http://www1.od.nih.gov/oma/manualchapters/intramural/3014/)		
8a.	Are all new protocols evaluated for suitability of enrollment of minorities, children and women?		
8b.	Has the IRB identified, on continuing reviews, any protocols with unsatisfactory enrollment of minorities, children and women?		
8c.	If YES, how many:		
8d.	What action was taken?		
9	Are all clinical protocols including natural history and epidemiology subjected to critical scientific review before being sent to the IRB?		
9a.	Who reviews:		
10	Do you assure that all new scientific staff in your IC complete the OHSR computer-based training program protecting human research subjects at the NIH? (http://ohsr.od.nih.gov/cbt/)		
10a.	How many staff have not completed this program:		
10b.	Please explain:		
10c.	Have all of your IRB members taken the Computer-Based Training (CBT) for NIH IRB members (http:ohsr.od.nih.gov/irb_cbt/)		
11	Do you involve your IC Clinical Director in determining and allocating resources for clinical research?		

12	Have you and your Clinical Director implemented the NIH Standards for Clinical Research within the NIH Intramural Research Program? (http://www.cc.nih.gov/ccc/clinicalresearch/index.html)		
13	Do all PIs on clinical protocols distribute to associate investigators the "Guide to Prevention of Conflict of Interest in Clinical Reseach? (http://www.nih.gov/campus/irnews/guidelines.htm)		
13a	If Pis do not distribute, how is the Guide distributed?		
14	Are potential conflicts of interest resolved before IRB members are appointed?		
15	Are all stored human samples with patient identifiers recorded in a database or other tracking system?		

B.	**RULES COVERING INVOLVEMENT OF INTRAMURAL SCIENTIST AND USE OF INTRAMURAL FACILITIES IN NIH-FUNDED EXTRAMURAL PROJECTS**		
		Yes	***No***
1	Are intramural scientists in your IC who are listed on a grant application as collaborating, or serving as consultants on an extramural NIH grant, submitting to you a copy of the letter of collaboration for advaced approval? (http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/IRP-ERP-Cover-memo-10-27-99.htm)		
2	Are you notifying the grants management office of the appropriate IC about collaborations involving your intramural scientists, that are such a substantial part of a grant application that it may need to be changed to a cooperative agreement (U01)?		
3	Have you approved of any significant use of NIH intramural facilities by Guest Researchers or Special Volunteers supported by extramural NIH funds, i.e., SBIR, or other Federal granting agency?		
3a.	If YES, how often:		
3b.	Was the grants management office of the IC (or other Federal granting agency) informed?		

C. BOARD OF SCIENTIFIC COUNSELOR (BSC) REVIEWS			
		Yes	***No***
1	Do you distribute the "Orientation Guidelines for Boards of Scientific Counselors" to all regular Board of Scientific Counselor members, and Ad Hoc consultants? (http://www1.od.nih.gov/oir/sourcebook/sci-review/Orientation%20Guide%209%2026%2005.pdf)		
2	Has any Principal Investigator/laboratory/branch gone un-reviewed for more than four years?		
2a.	If YES, please justify non-review:		
3	For each laboratory reviewed during the period of review, were all tenured senior investigators and all tenure-track investigators reviewed?		
3a.	If NO, please justify non-review:		
4	Do you report to the BSC your actions in response to their recommendations?		
4a.	Were any recommendations by the BSC not addressed by the Scientific Director?		
4b.	Does someone from your IC report on the BSC evaluation of intramural research to the IC National Advisory Council annually?		
5	Do you have reviewers with clinical research expertise on your BSC?		
5a.	Are clinical protocols reviewed by your BSC or a subgroup of your BSC?		
6	Do you provide your BSC with lists of fellows who have left your IC since the last review, along with the position that they have taken?		
7	Is your BSC reviewing and commenting on the quality of the mentoring provided by each PI to his/her trainees?		
8	Is your BSC reviewing and commenting on the quality of the mentoring received by each tenure-track investigator?		

D. ANIMAL CARE AND USE (answer with assistance of ACUC chair)			
		Yes	***No***
1	Does your IC have a properly constituted ACUC or access to a properly constituted ACUC (under a formal contractual agreement) that meets regularly to review Animal Study Proposals (ASP)?		
1a.	Is there a nonaffiliated community member appointed to your ACUC (or the ACUC that supports your IC under a formal contractual agreement)?		
1b.	How many Animal Study Proposals were approved on the first round _____; tabled for revision or re-review _____ ?		
1c.	How many Animal Study Proposals were disapproved _____?		
2	Were there any animal-related incidents (include ASP or investigator privileges revoked or suspended) required to be reported to OLAW during FY2005?		
2a.	If YES, please explain:		
3	Does a system exist to verify that all appropriate staff receives introductory and triennial refresher training in the care and use of animals (e.g., PI & Animal Users Course)? (http://oacu.od.nih.gov/training/index.htm)		
4	Have all projects that require NIH Institutional Biosafety Committee (IBC) approval been reviewed and approved by the IBC prior to the initiation of animal work?		
4a.	Have all projects that require NIH Division of Radiation Safety (DRS) approval been reviewed and approved by the DRS prior to the initiation of animal work?		
5	Does a system exist to asure that staff having direct contact with animals, their viable tissues, body fluids, wastes, or living quarters are enrolled in the Animal Exposure Surveillance Program (AESP)?		
6	Were any major/significant deficiencies found during the ACUC semi-annual program review or inspection of your animal facilities?		
6a.	Describe the resolution of these deficiencies:		
7	Has the IC veterinarian, or other source, reported to you or the IC ACUC any instances of facility management deficiencies that would threaten AAALAC accreditation?		

7a	Describe the resolution of these deficiences:		
8	Do you meet with the ACUC Chair twice a year to review your IC Animal Care and Use program?		
9	Does your ACUC Chair or Vice Chair attend meetings of the NIH Animal Research Advisory Committee on a regular basis?		
10	Did the ACUC review IC animal(s) activities in shared/central facilities?		
10a.	Were all noted deficiencies corrected to the ACUC's satisfaction?		
10b.	Did one or more members of the ACUC conduct visits during FY2005 to all IC areas where animal activities are performed?		
11	Did all new ACUC members receive their required training?		
12	Were all scientific staff, including students, Guest Researchers, Special Volunteers and contractors who work with animals, identified and enrolled in AESP (or equivalent program) and given required training?		
13	Do you provide support for the ACUC to have a coordinator?		
14	Do you provide funding for your ACUC chair and/or other ACUC members to attend ACUC oriented or continuing education courses and/or workshops, e.g., OLAW Workshops or PRIM & R Meetings?		
15	Are co-investigators and users provided sufficient opportunity to acquire training and experience in animal procedures associated with IC ASPs? Co-investigator is defined as individuals (other than the PI) who perform animal activities described in any particular protocol.		
16	Does the ACUC fulfill its responsibilities regarding oversight of animal activities performed at contract sites, as outlined in Policy Manual 3040-3 (http://www1.od.nih.gov/oma/manualchapters/intramural/3043-1/)?		

17	Does the ACUC assure that staff members who work with awake behaving nonhuman primates have received all necessary training and achieved competency in those procedures, as outlined in Policy Manual 3044-2 (http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/)?		

E. SCIENTIFIC MISCONDUCT			
		Yes	***No***
1	Does your organization use approved NIH procedures to define misconduct and to report allegations? (http://www1.od.nih.gov/oir/sourcebook/ResEthicsCases/NIH%20Misconduct2.pdf)		
1a.	Has each member of your scientific staff been provided a copy of the publication: "A Guide to the Handling or Scientific Misconduct Allegations in the Intramural Research Program at the NIH? (http://www1.od.nih.gov/oir/sourcebook/ResEthicsCases/NIH%20Misconduct2.pdf)		
2	Is research ethics/scientific conduct training, using case discussions, provided by the IC yearly?		
2a.	How many people took the training in FY2005?		
	Senior Investigators:		
	Investigators:		
	Senior Scientists/Senior Clinicians:		
	Research Fellows/Clinical Fellows:		
	Staff Scientists/Staff Clinicans:		
	Senior Research Assistants/Research Assistants:		
	Post-baccalaureate Fellows:		
	Graduate Students:		
	Technical IRTAs:		
	Contract staff:		
2c.	Have all current Intramural staff taken the "Research Ethics" online course? (http://researchethics.od.nih.gov/)		
3	Who is the designated official for receiving allegations of scientific misconduct? Name and phone number:		
4	Did the designee receive any allegations during the period of review?		
4a.	Were all of these allegations addressed?		
4b.	Were all such allegations brought to the attention of the Agency Intramural Research Integrity Officer (AIRIO) in the Office of Intramural Research?		
5	What was the disposition of the allegation(s):		
5a.	Proceeded to inquiry stage?		
5b.	Proceeded to investigation stage?		

6	Were any allegations of inappropriate authorship raised during the period of review?		
6a.	If YES, how many:		
7	Have research resources (equipment, personnel, and space) been diverted to prohibited activities (i.e., violations of the Antideficiency Act)?		
7a.	If YES, please describe corrective action taken:		
8	Do you inform personnel that unauthorized removal of government records, equipment, and laboratory reagents is illegal (e.g., removal of government property without a duly authorized loan agreement or property pass)?		
8a.	Are you aware of any incidents of illegal removal of government property in FY2005?		
8b.	If YES, please describe corrective action taken:		
8c.	Are all intramural staff aware of restrictions associated with traveling with research materials? (http://www1.od.nih.gov/oir/sourcebook/oversight/departurememo.htm)		

F. ADMINISTRATIVE PROCEDURES			
		Yes	***No***
1	Do you have a mechanism to notify all new staff of the requirement to complete the NIH Online Orientation Program? (http://orientation.nih.gov)		
1a.	Has someone been designated to follow up and ensure that everyone completes this training?		
2	Do you distribute copies of the following to all new scientific staff: NIH Guide to Training and Mentoring? (http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/TrainingMentoringGuide_7.3.02.pdf)		
2a.	Guidelines for the Conduct of Research (http://www.nih.gov/campus/irnews/guidelines.htm)?		
2b.	Guidelines for the Conduct of Research Involving Human Subjects at the NIH (http://ohsr.od.nih.gov/guidelines/GrayBooklet82404.pdf)?		
3	Who is reponsible in your IC to ensure that dual payment of personnel does not occur? Name and phone number:		
3a.	Were there instances during FY2005 when personnel have been paid under two systems?		
3b.	If YES, please describe:		
4	Do you have a procedure for clearance of manuscripts, as specified by the Board of Scientific Directors? (Procedures should contain elements as found in: http://www1.od.nih.gov/oir/sourcebook/oversight/pub-clear.htm)		
5	Who is reponsible in your IC to asure that IPA agreements have been signed? Name and phone number:		
6	Are all contract workers (CWSs, CWAs, and CWTs) hired as specified in: http://www1.od.nih.gov/oir/sourcebook/irp-policy/contractproposal.htm?		
6a.	Are appointments of contract workers (CWSs, CWAs, and CWTs) reported to OIR as specified? (http://www1.od.nih.gov/oir/sourcebook/irp-policy/contractproposal.htm)		
7	How many of your laboratories requiring Clinical Laboratory Improvement Act (CLIA) certification to conduct diagnostic tests were identfied:		
7a.	Applied for certification:		
7b.	Received certification:		

8	Do you inform all new personnel, including trainnes, about the Government-wide restrictions regarding:		
8a.	Human fetal tissue procurement? (http://www1.od.nih.gov/oir/sourcebook/oversight/human-tissue-oversight.htm)		
8b.	Human embryonic stem cell research? (http://www1.od.nih.gov/oir/sourcebook/oversight/stemcell.update.htm)		
8c.	Do you have a procedure in place to ensure the OIR is notified of every purchase of human embryonic stem cell lines (http://www1.od.nih.gov/oir/sourcebook/oversight/stemcellchecklist-11-21.pdf)?		
9	Have you developed formal checkout procedures (i.e., checklist, database, or clearance form) for departing staff?		
9a.	Are departing staff aware of the rules regarding transfer of government property? (http://www1.od.nih.gov/oir/sourcebook/oversight/departurememo.htm)		
10	Are your researchers encouraged to use the on-line application system to fill post-baccalaureate, summer and post-doctoral positions? (http:www.//training.nih.gov)		
11	Have all staff been informed of restrictions associated with the use of NIH letterhead to write letters of reference?		
12	Have you worked with your CIO and CIT to verify that all mission-critical databases and systems are backed up in case in an event that would interrupt normal opertations?		